

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (“Agreement”) is entered into between the United States of America, acting through the United States Department of Justice and on behalf of the United States Food & Drug Administration (“FDA”), United States Department of Veterans Affairs (“VA”), and the United States Department of Defense (“DoD”), (collectively, “the United States”), Relator Dr. Julie Kazimiroff (“Relator”), and Dentsply International Inc. (“Dentsply”), (hereafter referred to as “the Parties”), through their authorized representatives. This Agreement resolves allegations that were brought under the qui tam provisions of the False Claims Act, 31 U.S.C. §§ 3729-3733, in United States of America ex rel. Dr. Julie Kazimiroff v. Dentsply International, Eastern District of Pennsylvania, No. 99-0423 (the “Civil Action”), and that were investigated by the United States, including the United States Offices of Inspector General of the FDA and VA, the Defense Criminal Investigative Service (“DCIS”), and the Naval Investigative Service (“NIS”).

II. PREAMBLE

As a preamble to this Agreement, the Parties state the following:

A. Dentsply, a Delaware corporation whose corporate headquarters are located in York, Pennsylvania, is the largest dental device manufacturer in the world. The Caulk Division of Dentsply, located in Milford, Delaware, has manufactured a variety of dental products, including Advance Hybrid Ionomer Cement (“Advance”), a dental cement; Aquasil, an impression material; and Dispersalloy, a filling material (collectively, the “Products”).

B. Dentsply sold Advance, Aquasil and Dispersalloy products to agencies of the United States directly through a Federal Supply Schedule contract with the VA and through other contracts with government agencies, including but not limited to the Department of Defense and Department of the Navy. The Advance, Aquasil and Dispersalloy products also were sold to agencies of the United States indirectly through distributors.

C. The Federal Supply Schedule contract between the VA and Dentsply required that all Dentsply products delivered under the contract “conform in every respect to the Federal Food, Drug, and Cosmetic Act and regulations promulgated under the Act.”

D. This Agreement covers civil claims the United States and Relator may pursue against Dentsply for alleged failure to comply with FDA statutes and regulations as alleged in the Civil Action and as investigated by the United States, hereinafter known as the “Covered Conduct. The term “Covered Conduct” is defined in Section II.(E), below.

E. The Covered Conduct consists of (i) the allegations of the United States and the Relator made in the Civil Action, including any potential violations of the Good Manufacturing Practices and Quality Systems Regulations related to the conduct alleged in the Civil Action; and (ii) the allegations of the United States and the Relator that Dentsply sold the Products to the United States that were not in conformance with the Federal Supply Schedule contract terms in that Dentsply failed to timely file Medical Device Reports as required by the Federal Food, Drug & Cosmetic Act and regulations promulgated under the Act for complaints reported by dentists who had used Advance on patients, some of whom experienced fractured teeth and roots, pulpal death, and cracked crowns.

F. The United States and Relator contend further that they have certain claims against Dentsply under the False Claims Act, 31 U.S.C. §§ 3729-3733, the Federal Food, Drug & Cosmetic Act, and common law doctrines for the Covered Conduct.

G. The United States also contends that it has certain administrative claims against Dentsply under the administrative monetary penalties provision of the Federal Food, Drug, & Cosmetic Act, 21 U.S.C. § 333(f)(1)(A), the civil penalties provisions of the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812, and civil monetary penalties provision of the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, for the Covered Conduct.

H. Dentsply disclaims any liability and denies the allegations and contentions of the United States and Relator as set forth herein and in the Civil Action.

I. To avoid the delay, uncertainty, inconvenience and expense of protracted litigation of the asserted claims, the Parties reach a full and final settlement as set forth herein.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in consideration of the mutual promises, covenants, and obligations set forth below, and for good and valuable consideration, the parties agree as follows:

1. Dentsply agrees to pay to the United States a total of Six Hundred Thousand Dollars (\$600,000.00) (the "Settlement Amount"). Dentsply agrees to make the payment of the Settlement Amount by electronic funds transfer pursuant to written instructions to be provided by Assistant U.S. Attorney Barbara Rowland. Dentsply agrees to make this electronic funds transfer by no later than within two business days of the effective date of this Agreement.

2. Subject to the exceptions of Paragraph 3 below, in consideration of the obligations of Dentsply set forth in this Agreement, conditioned upon Dentsply's payment in full of the

Settlement Amount, and subject to Paragraph 8, below (concerning bankruptcy proceedings commenced within 91 days of the effective date of this Agreement), the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release Dentsply, and its agents, directors, officers, employees, and representatives, from any civil or administrative claim the United States has or may have under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; the Federal Food, Drug & Cosmetics Act, 21 U.S.C. §§ 301-397, or the common law theories of payment by mistake, unjust enrichment, breach of contract and fraud, for the Covered Conduct.

3. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Dentsply) are any and all of the following:

(1) Any civil, criminal or administrative claims arising under Title 26, United States Code (Internal Revenue Code);

(2) Any criminal liability;

(3) Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs for any conduct other than the Covered Conduct;

(4) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

(5) Any claims based upon such obligations as are created by this Agreement;

(6) Any claims for personal injury or property damage or for other actual damages arising from the Covered Conduct; and

(7) Any claims based on a failure to deliver items or services due.

4. Dentsply waives and will not assert any defenses Dentsply may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on the Double Jeopardy or Excessive Fines Clause of the Constitution or the holding or principles set forth in United States v. Halper, 490 U.S. 435 (1989), and Austin v. United States, 113 S. Ct. 2801 (1993). Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue Laws, Title 26 of the United States Code.

5. Dentsply agrees that all costs (as defined in the Federal Acquisition Regulation (“FAR”) § 31.205-47, and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ddd (1997) and §§ 1396-1396v (1997), and the regulations promulgated thereunder) incurred by or on behalf of Dentsply in connection with: (1) the matters covered by this Agreement; (2) the Government’s audit(s) and investigation of the matters covered by this Agreement; (3) Dentsply’s investigation, defense, and corrective actions undertaken in response to the Government’s audit(s) and investigation in connection with the matters covered by this Agreement (including attorneys fees); (4) the negotiation of this Agreement; and (5) the payment made pursuant to this Agreement are unallowable costs on Government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, Veterans Affairs Program, and Federal Employee Health Benefits Program (“FEHBP”) (hereafter “unallowable costs”). Dentsply will not charge such unallowable costs directly or indirectly to any contracts with the United States or any state Medicaid program, or seek payment for such unallowable costs through

any cost report, cost statement, information statement, or payment request submitted by Dentsply or any of its subsidiaries to the Medicare, Medicaid, VA or FEHBP programs.

6. This Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not create or release any claims in or against any other person or entity.

7. Dentsply expressly warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. § 547(b)(3), and will remain solvent following its payment of the Settlement Amount to the United States. Further, the Parties expressly warrant that, in evaluating whether to execute this Agreement, the Parties (1) have intended that the mutual promises, covenants and obligations set forth in the Agreement constitute a contemporaneous exchange for new value given to Dentsply, within the meaning of 11 U.S.C. § 547(c)(1), and (2) have concluded that these mutual promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange.

8. In the event Dentsply commences, or a third party commences, within 91 days of the effective date of this Agreement, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization or relief of debtors (a) seeking to have any order for relief of Dentsply's debts, or seeking to adjudicate Dentsply as bankrupt or insolvent, or (b) seeking appointment of a receiver, trustee, custodian or other similar official for Dentsply or for all or any substantial part of Dentsply's assets, Dentsply agrees as follows:

a. Dentsply's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547, and Dentsply will not argue or otherwise take the position in any such case, proceeding or action that: (i) Dentsply's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) Dentsply was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States hereunder; or (iii) the

mutual promises, covenants and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to Dentsply.

b. In the event that Dentsply's obligations hereunder are avoided pursuant to 11 U.S.C. § 547, the United States, at its sole option, may rescind the releases in this Agreement, and bring any civil and/or administrative claim, action or proceeding against Dentsply for the claims that would otherwise be covered by the releases provided in Paragraph 2, above. If the United States chooses to do so, Dentsply agrees that (i) any such claims, actions or proceedings brought by the United States (including any proceedings to exclude Dentsply from participation in Medicare, Medicaid, or other federal health care programs) are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case or proceeding described in the first clause of this paragraph, and that Dentsply will not argue or otherwise contend that the United States' claims, actions or proceedings are subject to an automatic stay; (ii) Dentsply will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories to any such civil or administrative claims, actions or proceedings that are brought by the United States within 30 calendar days of written notification to Dentsply that the releases herein have been rescinded pursuant to this paragraph, except to the extent such defenses were available on the effective date of this Agreement; and (iii) the United States may pursue all available remedies, including damages and penalties, for its claims based upon the Covered Conduct in the case, action or proceeding referenced in the first clause of this paragraph, as well as in any other case, action or proceeding.

c. Dentsply acknowledges that its agreements in this paragraph are provided in exchange for valuable consideration provided in this Agreement.

9. The United States will, pursuant to 31 U.S.C. § 3730(d)(1), pay Relator a share of the Settlement Amount made to it, within a reasonable time of its receipt of same from Dentsply. The United States has no obligation to disburse any monies to Relator unless and until the United States receives the Settlement Amount from Dentsply.

10. Pursuant to 31 U.S.C. § 3730(d), Dentsply shall pay Relator's attorneys' fees and costs in an amount reached by separate agreement between Relator and Dentsply.

11. Relator agrees that this settlement is fair, adequate and reasonable under all of the circumstances, and will not challenge this Agreement under 31 U.S.C. § 3730(c)(2)(B).

12. In consideration of the mutual promises and obligations of this Agreement, and in consideration of the separate resolution by agreement of the issues between Relator and Dentsply concerning Relator's attorneys' fees and costs, Relator and each of her agents, representatives, heirs, administrators, executors, successors or assigns, do hereby fully release and forever discharge Dentsply, its parents, subsidiaries, affiliates, officers, directors, employees, representatives, successors and assigns, of and from any and all claims that were brought, or could have been brought, in the Civil Action, and any and all other manner of actions, causes of action, suits, debts, accounts, covenants, contracts, agreements, judgments, demands and any claims whatsoever in law or equity, whether or not heretofore known, suspected or asserted. Relator further agrees that she releases the United States from any and all claims that were brought, or could have been brought, in the Civil Action and, in connection with the United States' investigation and resolution of the Civil Action.

13. In consideration of the mutual promises and obligations of this Agreement, and in consideration of the separate resolution by agreement of the issues between Relator and Dentsply concerning Relator's attorneys' fees and costs, Dentsply, its parents, subsidiaries, affiliates,

officers, directors, employees, representatives, successors and assigns, do hereby fully release and forever discharge Relator and each of her agents, representatives, heirs, administrators, executors, successors or assigns, of and from any and all claims that could have been brought in connection with the filing of the Civil Action, and any and all other manner of actions, causes of action, suits, debts, accounts, covenants, contracts, agreements, judgments, demands and any claims whatsoever in law or equity, whether or not heretofore known, suspected or asserted.

14. The Parties agree that in consideration of Dentsply's payment in full of the Settlement Amount and separately agreed upon attorneys' fees and costs, the Parties will submit to the Court a Joint Stipulation of Dismissal and Order agreeing that the Civil Action should be dismissed with prejudice.

15. Each party to this Agreement will bear its own legal and other costs incurred in connection with this matter, except as referenced in Paragraph 10 above, including the preparation and performance of this Agreement.

16. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement will be the United States District Court for the Eastern District of Pennsylvania.

17. This Agreement constitute(s) the complete agreement between the Parties. This Agreement may not be amended or modified except in a writing signed by the affected Parties.

18. The undersigned individuals signing this Agreement on behalf of Dentsply represent and warrant that they are authorized by Dentsply to execute this Agreement. The undersigned United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

19. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement.

20. This Agreement is effective on the date of signature of the last signatory to the Agreement.

THE UNITED STATES OF AMERICA

PATRICK J. MEEHAN
United States Attorney

DATE:_____

BY:_____
VIRGINIA A. GIBSON
Assistant United States Attorney
Chief, Civil Division

DATE:_____

BY:_____
BARBARA ROWLAND
Assistant United States Attorney

DENTSPLY INTERNATIONAL INC. – DEFENDANT

DATE:_____

BY:_____
Officer
Dentsply International Inc.

DATE:_____

BY:_____
RICHARD L. SCHEFF, ESQ.
Montgomery McCracken Walker &
Rhoads, LLP

RELATOR

DATE: _____

BY: _____

DR. JULIE KAZIMIROFF
Relator

DATE: _____

BY: _____

L. FELIPE RESTREPO, ESQ.
Krasner & Restrepo

DATE: _____

BY: _____

LARRY KRASNER, ESQ.
Krasner & Restrepo

DATE: _____

BY: _____

Kairys, Rudovsky, Epstein,
Messing & Rau